

## EXHIBIT “B”



DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE  
PUBLIC HEALTH SERVICE  
FOOD AND DRUG ADMINISTRATION  
WASHINGTON, D.C. 20204

October 30, 1979

Mr. Daniel P. Thompson  
Bonner, Thompson, O'Connell & Gaynes  
900 Seventeenth Street, N.W.  
Washington, D.C. 20006

Dear Mr. Thompson:

During our conference with you and Mr. Anthony Filandro, Vice President of Virginia Dare Extract Company, Inc., of Brooklyn, New York, on October 19, 1979 you raised a question concerning category II vanilla flavor in ice cream. You requested that we reply to your question in writing.

The ice cream standard under 21 CFR 135.110(e)(5)(i) states that an artificial flavor simulating the characterizing flavor shall be deemed to predominate in the case of vanilla beans or vanilla extract used in combination with vanillin, if the amount of vanillin used is greater than one ounce per unit of vanilla constituent as that term is defined in §169.3(c). Consequently, an ice cream manufacturer could not call his product "vanilla flavored ice cream" (Category II) if the flavor consisted of one ounce of vanillin per unit of vanilla constituent and any flavor from a non-vanilla bean source (which simulates, resembles, or reinforces the vanilla flavor) is added to the product. The non-vanilla flavor is deemed to simulate vanilla if the addition of the non-vanilla flavor results in a reduction in the amount of vanilla bean derived flavor that would otherwise be used in a vanilla flavored ice cream. Ice cream made from such a product would come under Category III and have to be labeled as "artificial vanilla".

We hope this adequately answers the question you raised at our meeting.

Sincerely yours,

*R. E. Newberry*  
R. E. Newberry  
Assistant to the Director  
Division of Regulatory Guidance  
Bureau of Foods